CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986
(PROPOSITION 65)

NOTICE TO INTERESTED PARTIES

March 12, 2004

ACRYLAMIDE WORK PLAN

Acrylamide is listed under the Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65; Health and Safety Code Section 25249.5 et seq.) as a chemical that is known to the state to cause cancer. A No Significant Risk Level (NSRL) for acrylamide of 0.2 micrograms/day was established in regulation in 1990 (Title 22, California Code of Regulations (CCR), Section 12705(c)). Recent research has shown that acrylamide can form during the cooking of certain foods at high temperatures. Accordingly, interested parties have asked the California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHHA), as the lead agency for the implementation of Proposition 65, to interpret the applicability of Proposition 65 regulations to acrylamide in foods.

This notice lays out a work plan for developing additional regulations to assist in Proposition 65 compliance for acrylamide exposures. In preparation of this plan, OEHHA held a public workshop on May 12, 2003, to explore appropriate Proposition 65 regulatory options regarding acrylamide created by cooking foods. Subsequent to the workshop, OEHHA developed a draft work plan, which reflected input received at the workshop, public health considerations, and the need for clear guidance to facilitate Proposition 65 compliance concerning acrylamide in foods. The draft work plan was released to the public for comment August 1, 2003 (*California Regulatory Notice Register*; Register 2003, No. 31-Z).

Consultation with the Carcinogen Identification Committee (CIC)

The evaluation of potential acrylamide risks in foods is challenging due to the chemical's pervasiveness and the degree of exposure to it in the diet. Therefore, OEHHA assigned a consultative role to the Carcinogen Identification Committee (CIC) in the draft work plan. This is consistent with the CIC's role as the State's Qualified Experts and its general powers and duties as set forth in Title 22, CCR, Section 12305(a)(5), and noted in Title 22, CCR, Section 12302(e). At a CIC meeting held October 17, 2003, OEHHA sought input from the CIC on the draft work plan, and specifically, its opinion on updating the NSRL. Opportunity for public comment on the proposed work plan was provided at this meeting, and through written submission prior to the meeting.

CIC and Public Comment on Proposed Work Plan

The final acrylamide work plan presented below reflects CIC and public comments received on the proposed work plan released August 1, 2003. The draft work plan proposed to develop a series of four regulations: 1) Update the NSRL for acrylamide (pursuant to 22 CCR 12705) and review data on foods causing exposure below the NSRL; 2) identify acrylamide levels in foods below the limit of detection (pursuant to 22 CCR 12901); 3) identify alternative acrylamide exposure levels for certain foods based on public health considerations (pursuant to 22 CCR 12703(b)); and 4) identify the appropriate form and content of Proposition 65 warnings required for foods due to acrylamide (pursuant to 22 CCR 12601(b)). Consistent with regulations, OEHHA also proposed to provide regulatory levels and advice regarding whether certain food items required warnings under Proposition 65, by application of 22 CCR Sections 12705, 12901, and 12721. The CIC and some members of the public strongly advised OEHHA not to undertake this activity, and this is reflected in the final work plan presented here. Objections raised included the level of state effort, resources and time required to ascertain which foods might require a warning under Proposition 65, the lack of specific exposure data, variability in acrylamide concentrations for given foods, and the numerous foods involved.

1) NSRL Update

The CIC recommended that OEHHA proceed with the work to update the NSRL. The CIC, at its October 2003 meeting, and the public through written and oral comments, recommended a number of factors to consider in updating the NSRL, including: the work of other national and international bodies generating and analyzing data pertinent to acrylamide dose-response; variability in susceptibility within the human population; the formation of DNA adducts subsequent to acrylamide intake; and the use of human data to obtain an upper bound estimate on the acrylamide dose-response relationship. It was also recommended that OEHHA consider the information being provided at the April 13-15, 2004 workshop, "Update: Scientific Issues, Uncertainties, and Research Strategies on Acrylamide in Food," held in Chicago under the sponsorship of the Food Industry Coalition and JIFSAN (Joint Institute for Food Safety and Applied Nutrition). In updating the NSRL, OEHHA will take into consideration the factors raised by the public and CIC and information presented at the Food Industry Coalition/JIFSAN workshop.

Information on the April 2004 Food Industry Coalition/JIFSAN workshop is provided on the webpage http://www.jifsan.umd.edu/acrylamide2004_anmt.htm. In October 2002, the food industry in conjunction with the JIFSAN, convened a workshop that resulted in the identification of a series of scientific research projects relevant to the assessment of the cancer risks of acrylamide in food. At the April 2004 workshop, the status and results of scientific research conducted globally on acrylamide in food since 2002 will be discussed and further research needs identified. Information pertinent to the development of the NSRL is likely to be presented at the April 2004 workshop.

2) Limits of Detection

OEHHA proposed to develop a regulation addressing the limit of detection of acrylamide in food per 22 CCR 12901. OEHHA heard about technical aspects of measuring acrylamide in food and the potential for detection limits to vary with different types of foods (e.g., solid versus liquid, high vs. low fat content). Because of the specificity that may be involved in determining the limit of detection for particular foods, and ongoing research and development in this area, OEHHA will not develop a general regulation regarding methods of detection at this time. To provide assistance in the near term, however, OEHHA invites requests for regulatory guidance via the Safe Use Determination (SUD) process, pursuant to 22 CCR 12204. A SUD involves the analysis of data provided by the requestor on specific products, chemical concentrations and exposures circumstances to determine whether such use results in exposures below the Proposition 65 regulatory threshold. While OEHHA has decided not to proceed at this time with a regulatory specification of methods and limits of detection for acrylamide, a SUD may entail the evaluation of a limit and method of detection for specific items and uses. Information required for OEHHA to evaluate safe use of an acrylamide-containing product under this provision will be specific to the particular food product. Those wishing to submit a request for a SUD are referred to the regulatory guidance for submission, processing and determination (22 CCR 12204).

3) Alternative Risk Levels

The third area of regulatory activity proposed by OEHHA involved the identification of foods for which sound considerations of public health may support alternative regulatory levels for acrylamide exposure (22 CCR 12703(b)). OEHHA heard strong objections to this proposal from the CIC and some members of the public and will not pursue it at this time. Objections raised included the potentially large expenditure of state resources required to determine alternative risk levels for specific foods and complexities in making an alternative risk determination given the large variability of acrylamide concentration in certain foods, difficulties in measuring acrylamide in food, and the challenge of factoring in the differing nutritional content of food in the analysis. In addition, some objecting spoke to the public's right to know about the cancer hazard of acrylamide in food, the lack of a scientific basis for establishing alternative risk levels, and the possible confusion that may result if findings were inconsistent with those of the U.S. Food and Drug Administration.

4) Safe Harbor Warnings

With regard to the fourth area of regulation, a number of suggestions were received from the CIC and public regarding the form and content of Proposition 65 warning messages. These included general public health messages broadcast by, for example, television on the formation of acrylamide during food preparation, acrylamide risks and the importance of a healthy diet, as well as periodic modification of such messages as the scientific information on acrylamide risks evolves. Suggestions and precautions regarding food product labeling were also heard. Several comments were also received regarding addressing other toxicity endpoints such as neurotoxicity and reproductive toxicity in conveying information on acrylamide risks.

Final Acrylamide Work Plan

OEHHA will take the following actions to address the acrylamide issue:

1. Acrylamide NSRL Update (Regulation). The NSRL for acrylamide (0.2 micrograms per day) was adopted in regulation in 1990. Since its adoption, additional scientific data have been published relevant to the cancer dose-response assessment. Pursuant to Title 22, CCR, Section 12705, OEHHA will review these data and, as appropriate, adopt an updated NSRL into regulation.

In developing a revised NSRL, OEHHA will review available scientific information on dose-response, including cancer bioassay, biomarker, and pharmacokinetic studies. OEHHA will also consider comments previously received from the CIC and public regarding factors to consider in updating the NSRL and information discussed at the April 2004 Food Industry Coalition/JIFSAN workshop on acrylamide discussed above.

OEHHA anticipates initiating the formal regulatory process by releasing in summer 2004 a proposed updated NSRL for acrylamide. As required by the Administrative Procedure Act (APA), this will be followed by a written 45-day public comment period, and a public hearing will be scheduled during that comment period.

After review and response to the public comments, OEHHA may adopt the NSRL and complete the regulatory process. In the alternative, OEHHA may revise the proposed NSRL. A revision would require an additional comment period (minimum 15-day), or request for further input through the scheduling of additional public comment periods and hearings. OEHHA anticipates adopting a revised NSRL in spring 2005, assuming only one comment period and hearing is required.

2. Form and Content for Proposition 65 Warnings Required Due to Acrylamide in Foods (Regulation). Without prejudging which foods may require a warning under Proposition 65, OEHHA is initiating the development of a regulation on the form and content of warnings for acrylamide in food where a warning is required. The goal of any such regulation would be to clarify the appropriate communication, in the appropriate context for warning consumers about the presence of acrylamide in the food in compliance with Proposition 65 and to avoid the dissemination of indiscriminate, misleading, confusing, or inappropriately alarming warnings.

OEHHA anticipates releasing a proposed safe harbor warning regulation in summer 2004. This will be a proposed addition to the regulation identifying the “safe harbor” form and content of a warning, and will specifically provide warning language for acrylamide in food that will be included in Title 22, CCR, Section 12601. This would initiate a formal APA regulatory process as described above. OEHHA anticipates adopting the regulation in summer 2005, assuming only one comment period and hearing is required.

Conclusion

OEHHA will give the development of the NSRL and warning regulations first priority in providing guidance for acrylamide in foods. As science develops or the need arises, additional regulatory activities may be undertaken by OEHHA to assist Proposition 65 compliance efforts. OEHHA will separately provide public notice for each of the regulatory actions described above.

If you wish to be on the list for notice of Proposition 65 regulatory actions on acrylamide, please contact:

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